

REMARKS

This Amendment is responsive to the non-final Office Action dated March 30, 2010. Applicant respectfully requests reconsideration of the rejections in view of the remarks below. In the application claims 29 - 36 are pending and each claim stands rejected under Adams et al., U.S. Patent Publication No. 2003/0132267 ("Adams"), alone or in combination with Deem, U.S. Patent No. 6,558,400.

Applicant addressed the prior rejections of the outstanding claims in its amendment of March 10, 2009. However, the Office Action failed to withdraw the rejections, instead placing the application's status on Final. Applicant filed its Rule 116 amendment on August 24, 2009 again pointing out the deficiencies in the pending rejections and requested that the rejections be withdrawn. An advisory action was entered, but the rejections were not withdrawn. The Applicant then filed its Pre-Appeal Request for review, again pointing out the errors in the rejections that rely on presently cited prior art. The panel acknowledged that the rejections were unsound and that prosecution was to be re-opened. It cannot be forgotten that all of this comes at a significant cost to the Applicant, who must continue to address questionable rejections that are ultimately withdrawn.

Now prosecution has been re-opened, and the new Office Action relies on the very same references that were found insufficient by the panel in the pre-appeal review. Applicant is again forced to draft a response and incur costs to address the new rejections based on the prior art previously found to be inadequate. Disappointingly, the current rejections still lack evidentiary foundation similar to the prior rejections.

Claim 29

Claim 29 is directed to a gastroplasty device that includes first and second tissue acquisition members, each acquisition member including a tissue receiving cavity, and a stapler. The Office Action states that Adams, not Deem, now teaches the first and second

acquisition members. Specifically, the Office Action argues that the stapler 17 is the first tissue acquisition member, and the anvil 10 is the second tissue acquisition member. There are several reasons why this is an incorrect interpretation of this claim. First, the combination of the stapler and anvil do not acquire tissue, but rather tissue must be brought to the staple/anvil combination. This combination has no ability to "acquire" tissue, unlike the claimed invention. Thus, these elements cannot properly be deemed tissue acquisition members and cannot satisfy the claim limitations.

Second, even if the term "acquisition" could be extended to the function performed by the stapler/anvil combination, the stapler/anvil combination must be considered one tissue acquisition member, not two. That is, the "anvil" cannot be deemed a "second" tissue acquisition member because the anvil does nothing without the stapler. Only by considering the stapler anvil together can there even be considered a "first" tissue acquisition member. Once this is properly construed, it is clear that there is no "second tissue acquisition member" as claimed, and Adams cannot be said to teach the claimed invention.

Also, the Office Action argues that the curved elements supporting the stapler and anvil constitute "tissue receiving cavities," although it would appear there is only one single "cavity." More critically, the claim calls for each cavity to be coupled to a vacuum port. The Office Action acknowledges that Adams' fails to teach this feature, but then argues that it would have been obvious to add this feature "to prevent debris from accumulating between the two acquisition members." However, using a vacuum would draw debris into the area, not prevent debris from entering the area. The Office Action's "rationale is supposedly based on the disclosure in paragraph [100] of Adams. However, Adams teaches that suction may be applied "through endoscope 8" but that a **shield 31** is necessary to prevent tissue or loose debris from being pulled near the mounting shafts 20a, 20b. [Adams, ¶100]. Therefore, it is not the suction as claimed by the Office Action that prevents debris, but rather the shield 31 due to the debris brought in by the suction.

So the Office Action's lone rationale for modifying Adams to include suction ports is flatly contradicted by the Adams' reference itself. Further, the embodiment relied upon by the Office Action has no mounting shafts 20a, 20b, which was the only reason to prevent the debris from entering the area, so there is no reason to be found in Adams from using the shield with respect to the embodiment of Figures 22 – 25, much less suction ports. It must be concluded that there is no reason that can be garnered from the Adams' disclosure that would support the proposed modification, and that the rejection must be considered the product of impermissible hindsight.

Also, since Adams teaches that suction is applied if at all via the endoscope, it must be concluded that Adams' taught away from the present invention of incorporating vacuum ports into the tissue acquisition cavities themselves. To propose otherwise would require a complete overhaul of the Adams' device without any recognized benefit and without any rationale to be found in the prior art itself. And since the position of the stapler in Figure 21 does not lend itself to the use of the endoscope to acquire tissue for stapling, the entire reasoning behind the rejection must be deemed faulty and cannot be the basis for a proper §103 rejection.

Further, there is no explanation in the Office Action for where it is taught that Adams teaches that each "cavity [is] sized to receive a fold of stomach tissue." There is nothing in Adams that would teach one of ordinary skill in the art that two folds of stomach tissue is accommodated in the stapler/anvil combination. It appears that the Office Action either ignored this limitation or gave it no weight. Yet stomach tissue has a known thickness, and thus the limitation would have a recognizable structural meaning to one of ordinary skill in the art, yet the Office Action provides no support for why Adams satisfies this limitation. Instead (again), the Office Action simply concludes what Adams fails to teach and offers nothing in the way of support to substantiate the assertions, forcing Applicant to again point out the deficiencies in the rejections.

In addition, the Office Action submits that the claimed "first tissue acquisition member" is Adams' stapler member 17. [Office Action, paragraph 2]. Claim 29 also calls for "a stapler disposed on the first tissue acquisition member." Thus, in order for Adams to satisfy the claim limitation as argued by the Office Action, there must be a stapler on the stapler member 17. Clearly, there is no stapler on the stapler member. And once again, the Office Action offers nothing in the way of explanation or cites to no structure to support the rejection. It simply concludes once again that the cited reference teaches the claimed limitations without explaining how a stapler is on the stapler.

Claims 30 – 36

The Office Action further acknowledges that Adams fails to teach the claimed septum. However, the Office Action argues that it would have been obvious to modify the Adams' stapler to include the septum of Deem "to damage contacting tissue to speed healing time." [O.A., page 3] However, Adams' uses a cutting blade to sever the tissue after it is stapled. The damage done to the tissue by cutting it with a blade would be far more extreme than anything that could be accomplished with Deems' septum, so once again the entire rationale for the proposed combination of Deem with Adams is incorrect when the disclosures are properly evaluated for what they teach. It is clear that no purpose would be served by adding the septum of Deem, and the rejection based on this proposed combination is without merit.

Further, in Deem two healthy walls of tissue are brought into proximity and stapled in order to form a permanent pouch. Because the walls are healthy, the abrasion from the septum is necessary to promote adhesion that will join the two sections of stomach brought in proximity by the Deem device. Conversely, in Adams a section of tissue is resected, so there is no need to induce "damage" to the tissue as claimed in the Office Action. Therefore, the proposed combination of Adams with Deem is not supported by the record, and is properly withdrawn.

The Office Action also argues that it would have been obvious to modify Adams as taught by Deem so as to include a balloon, citing column 8 of Deem. However, Deem teaches the balloon to stabilize the bougie, a marking instrument, not the stapler. Since Adams does not use a bougie, the teaching in Deem is of no assistance to the Office Action in suggesting that Adams would obviously be modified to include a balloon, particularly when the balloon/bougie combination of Deem is withdrawn before the stapler is ever inserted into the stomach (Col. 8, lines 50-51).

Applicant respectfully requests that, in view of the foregoing, the rejections be withdrawn and the claims as pending be allowed. If the Examiner believes that a telephone conference will further the prosecution of this case, the Examiner is kindly invited to contact the undersigned at the number below.

The Commissioner is authorized to charge any deficiencies or fees in connection with this preliminary amendment to Deposit Account No. 06-2425.

Respectfully submitted,
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